

Application Number: 09/879,517

Reply To Office Action of JANUARY 11, 2005**Amendments to the Claims**

1. (Currently Amended) A cartridge for a manually actuated respiratory medicament delivery device, comprising:
a body having opposed ends,
a passage through said body through said opposed ends wherein said opposed ends of said body surrounding said passage are convex,
a medicament stored in said passage and burstable polyolefin membranes having a burst pressure less than 10 atmospheres covering wherein said burstable polyolefin membranes are stretched taut over said convex opposed ends and are sealing said passage at said opposed ends of said body.
2. (Canceled)
3. (Currently Amended) The cartridge for a respiratory medicament delivery device as defined in Claim [2]1, wherein said opposed ends of said body are frustoconical adjacent said passage.
4. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 1, wherein said burstable membranes are formed of oriented polyolefin film and said oriented polymeric film covering and sealing said passage at said opposed ends of said body portion are oriented at different angles.
5. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 4, wherein said oriented polyolefin film at said opposed ends of said body portion are oriented at approximately right angles.
6. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 1, wherein said passage through said body of said cartridge is generally cylindrical.

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7. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 6, wherein said body of said cartridge is generally cylindrical and said body includes an annular groove at a midportion of said body.
8. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 1, wherein said medicament is a powdered medicament.
9. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 1, wherein said burstable polyolefin membranes are formed of polyethylene film having a thickness of between 0.3 and 1.5 mils and a burst pressure of less than 5 atmospheres.
10. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 9, wherein said polyethylene film is uniaxially oriented polyethylene film having draw ratio of at least 1.2.
11. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 10, wherein said uniaxially oriented polyethylene film at said opposed ends of said body are oriented at approximately right angles.
12. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 1, wherein said burstable polyolefin membranes have a burst pressure of less than 5 atmospheres.
13. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 1, wherein said burstable polyethylene membranes have a burst pressure of between 1.5 and 4 atmospheres.

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14. (Previously Presented) A cartridge for a manually actuated respiratory medicament delivery device, comprising:

- a body having opposed ends,
- a passage extending through said body through said opposed ends,
- a medicament stored in said passage, said opposed ends of said body having a convex surface surrounding said passage,
- and burstable polymeric films stretched taut over and bonded to said convex surfaces at said opposed ends of said body sealing said passage.

15. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 14, wherein said burstable polymeric film at said opposed ends of said body are oriented polyolefin films and said films over said opposed ends of said body are oriented at different angles.

16. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 15, wherein said burstable polyolefin films are oriented at about right angles relative to one another.

17. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 14, wherein said passage through body is generally cylindrical.

18. (Original) The cartridge for a medicament delivery device as defined in Claim 14, wherein said medicament is a powdered medicament.

19. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 14, wherein said burstable polymeric film are formed of polyethylene having a thickness of between 0.3 and 1.5 mils and having a burst pressure of between 1.2 and 10 atmospheres.

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20. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 19, wherein said polyethylene films are preferentially oriented polyethylene films having a burst pressure at less than 5 atmospheres.

21. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 20, wherein said preferentially oriented polyethylene films bonded to said convex surfaces at said opposed ends of said body are oriented at different angles.

22. (Original) The cartridge for a respiratory medicament delivery device as defined in Claim 21, wherein said preferentially oriented polyethylene films are oriented at approximately right angles to one another.

23. (Original) A medicament respiratory delivery device, comprising:
a housing having a chamber therein, an inlet port communicating with said chamber and an outlet port communicating with said chamber generally coaxially aligned with said inlet port;
a cartridge located within said chamber of said housing having opposed ends, a passage extending through said cartridge through said opposed ends of said cartridge generally coaxially aligned with said as inlet and outlet ports of said housing, a medicament in said passage, and thin burstable polyolefin membranes having a burst pressure of less than 10 atmospheres covering said passage, and bonded to said opposed ends of said cartridge, sealing said passage.

24. (Original) The medicament respiratory delivery device as defined in Claim 23 wherein said inlet port includes an inlet tube communicating with said chamber having a Luer connector adapted to threadably receive a syringe barrel for supplying fluid through said inlet tube to said cartridge to substantially simultaneously burst said polyolefin membranes and delivery said medicament through said outlet port.

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25. (Original) The medicament respiratory delivery device as defined in Claim 23, wherein said outlet port includes an outlet tube communicating with said chamber having a generally conical internal surface forming an exit diffuser.

26. (Original) The medicament respiratory delivery device as defined in Claim 23, wherein said housing is formed of two releasably interconnected components and one of said components includes a generally cylindrical chamber receiving said cartridge.

27. (Original) The medicament respiratory delivery device as defined in Claim 23, wherein said opposed ends of said cartridge surrounding said passage are convex and said burstable polyolefin membranes comprise polyolefin film having a thickness of between 0.3 and 1.5 mils stretched taut over each of said convex surfaces at said opposed ends of said end bonded to said convex surfaces, sealing said passage having a burst pressure of less than 5 atmospheres.

28. (Original) The medicament respiratory delivery device as defined in Claim 27, wherein said polyolefin film is a preferentially oriented polyolefin film and said oriented polyolefin film stretched over said opposed ends of said cartridge are oriented at different angles.

29. (Original) The medicament respiratory delivery device as defined in Claim 28, wherein said oriented polyolefin film is a uniaxially oriented polyethylene film, wherein said uniaxially oriented polyethylene film on one of said opposed ends of said cartridge is oriented at approximately right angles to the uniaxially oriented polyethylene film on the opposed end of said cartridge.

30. (Original) The medicament respiratory delivery device as defined in Claim 23, wherein said housing is formed of two opposed thermoformed polymeric sheets bonded

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together, and wherein said cartridge is encapsulated between said sheets forming said chamber.

31. (Original) The medicament respiratory delivery device as defined in Claim 30, wherein said medicament respiratory delivery device includes a manually actuated pressure actuator integrally formed from at least one of said sheets.

32. (Original) The medicament respiratory delivery device as defined in Claim 31, wherein said pressure actuator is a generally spherical bulb formed between said sheets and symmetrical with said inlet.

33. (Original) The medicament respiratory delivery device as defined in Claim 30, wherein said medicament respiratory delivery device includes a pressure actuator formed between said sheets communicating with said inlet and a generally cone-shaped diffuser formed between said sheets communicating with said outlet.

34. (Original) The medicament respiratory delivery device as defined in Claim 33, wherein said pressure actuator is bulb-shaped coaxially aligned with one of said burstable membranes and said cone-shaped diffuser is coaxially aligned with an opposed burstable membrane.

35. (Original) The medicament respiratory delivery device as defined in Claim 23, wherein said thin burstable polyolefin membranes have a burst pressure of less than 5 atmospheres.

36. (Original) A medicament respiratory delivery device, comprising:
a housing including an inlet member having a tubular inlet communicating with a generally cylindrical chamber and an outlet member having a tubular outlet port communicating with said chamber generally coaxially aligned with said tubular inlet; and
a generally cylindrical cartridge located within said chamber having opposed ends, a passage extending through said cartridge through said opposed ends generally coaxially

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aligned with said tubular gas inlet and outlet of said housing, a medicament in said cartridge, and burstable polyolefin membranes having a burst pressure of between 1.2 and 10 atmospheres stretched taut over said opposed ends of said cartridge and bonded to said opposed ends, sealing said passage.

37. (Original) The medicament respiratory delivery device as defined in Claim 36, wherein said burstable polyolefin membranes each comprise preferentially oriented polyolefin film and said preferentially oriented polyolefin film on said opposed ends of said cartridge are oriented at different angles having a burst pressure of less than 5 atmospheres.

38. (Original) The medicament respiratory delivery device as defined in Claim 37, wherein said preferentially oriented polyolefin film on said opposed ends of said cartridge are oriented at approximately right angles.

39. (Original) The medicament respiratory delivery device as defined in Claim 36, wherein said medicament is a powdered medicament.

40. (Original) The medicament respiratory delivery device as defined in Claim 36, wherein said tubular gas inlet includes a Luer connector adapted to receive the barrel of a syringe, whereby actuation of said syringe generates pressure through said tubular gas inlet to burst said burstable membranes and deliver said medicament to said outlet part.

41. (Original) The medicament respiratory delivery device as defined in Claim 36, wherein said burstable polyolefin membranes have a thickness of between 0.5 and 1.5 mils.

42. (Original) The medicament respiratory delivery device as defined in Claim 41, wherein said polyolefin membranes are formed of polyethylene film having a burst pressure of less than 5 atmospheres.

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43. (Original) The medicament respiratory delivery device as defined in Claim 42, wherein said polyethylene film has a burst pressure of between 1.5 and 4 atmospheres.

44. (Original) A medicament respiratory delivery device, comprising:
a housing comprised of two opposed bonded thermoformed thermoplastic sheets, said sheets having formed therebetween a chamber, an inlet communicating with said chamber, a collapsible pressure actuator having an outlet communicating with said inlet of said chamber and an outlet communicating with said chamber opposite said inlet of said chamber; and
a medicament cartridge in said chamber encapsulated by said sheets, said medicament cartridge including a body having opposed first and second ends, a passage extending through said body through said opposed first and second ends aligned with said inlet and outlet of said housing, a medicament in said passage, and burstable membranes covering said first and second ends of said passage, whereby delivery of fluid under pressure from said collapsible pressure actuator through said inlet of said housing ruptures said burstable membranes and delivers said medicament to said outlet of said housing.

45. (Original) The medicament respiratory delivery device as defined in Claim 44, wherein said collapsible pressure actuator formed between said sheets is generally spherical and symmetrical relative to said outlet of said collapsible pressure actuator.

46. (Original) The medicament respiratory delivery device as defined in Claim 44, wherein said burstable membranes are thin polyolefin sheets stretched taut over said first and second ends of said body and bonded to said first and second ends.

47. (Original) The medicament respiratory delivery device as defined in Claim 46, wherein said first and second ends of said body are convex and said polyolefin sheets have a burst pressure of less than 10 atmospheres.

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48. (Original) The medicament respiratory delivery device as defined in Claim 46, wherein said polyolefin sheets are formed of polyethylene having a thickness between 0.3 and 1.5 mils.

49. (Original) The medicament respiratory delivery device as defined in Claim 48, wherein said polyethylene sheets forming said burstable membranes are preferentially oriented polyethylene sheets having a burst pressure of less than 5 atmospheres and wherein said preferentially oriented polyethylene sheets on said first and second ends of said body are oriented at approximately right angles.

50. (Original) The medicament respiratory delivery device as defined in Claim 44, wherein said body of said cartridge includes an integral radial flange extending between and bonded to said opposed thermoplastic sheets forming said housing.

51. (Original) The medicament respiratory delivery device as defined in Claim 44, wherein said body of said cartridge is generally cylindrical and said chamber is generally cylindrical, conforming to the shape of said body.

52. (Withdrawn) A method of making a cartridge for a medicament respiratory delivery device comprising the following steps:
forming a cartridge having first and second ends and a passage through said first and second ends of said cartridge;
forming a thin polymeric film over said passage through said first end of said cartridge, sealing said passage through said first end;
inserting a medicament into said passage through said second end of said cartridge; and
stretching a thin polyolefin film having a burst pressure of less than 10 atmospheres over said second end of said cartridge and bonding said thin polyolefin film to said second end of said cartridge, sealing said passage through said second end.

53. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 52, wherein said method includes forming said second

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end of said cartridge with a convex surface surrounding said passage and stretching ~~said~~ thin polyolefin sheet taut over said passage and said convex surface surrounding ~~said~~ passage, and bonding said thin a polyolefin film to said convex surface.

54. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 52, wherein said method includes bonding said ~~thin~~ polyolefin film to said convex surface by applying a heated die to said thin polyolefin film, heat bonding said thin polyolefin sheet to said convex surface.

55. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 52, wherein said method includes stretching taut a thin polyolefin sheet having a thickness of between 0.3 and 1.5 mils and a burst pressure of between 1.2 and 10 atmospheres over said first end of said cartridge and bonding said film to said first end.

56. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 55, wherein said method includes forming said cartridge having generally conical surfaces at said first and second ends surrounding said passage and stretching a thin polyolefin film taut over said generally conical surfaces at said first and second ends of said cartridge and bonding said polyolefin films to said generally conical surfaces.

57. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 56, wherein said method includes heat bonding polyethylene films to said generally conical surfaces at said opposed ends of said cartridge.

58. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 52, wherein said method includes forming a generally cylindrical passage through said cartridge through said first and second ends.

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59. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 52, wherein said method includes stretching a thin preferentially oriented polyethylene film over said second end of said cartridge and heat bonding said preferentially oriented polyethylene film on said second end of said cartridge.

60. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 59, wherein said method includes sealing said passage through said first end of said cartridge by stretching a thin preferentially oriented polyethylene film over said first end of said cartridge, wherein said thin preferentially oriented polyethylene film over said first end of said cartridge is oriented at approximately right angles to said thin preferentially oriented polyethylene film stretched over said second end of said cartridge.

61. (Withdrawn) A method of making a cartridge for a medicament respiratory delivery device comprising the following steps:
forming a polymeric cartridge having opposed first and second ends, a passage through said cartridge and a convex surface surrounding said passage through said second end of said cartridge and said passage extending through said cartridge through said first and second ends for receipt of a medicament;
forming a thin polymeric film over said passage through said first end of said cartridge, sealing said passage through said first end; and
stretching a thin polyolefin sheet having a burst pressure of less than 10 atmospheres taut over said convex surface at second end and heat bonding said thin burstable polyolefin sheet to said second end of said polymeric cartridge.

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62. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 61, wherein said method includes forming said convex surface at said second end of said polymeric cartridge with a frustoconical surface surrounding said passage and stretching taut said thin burstable polyolefin film over said frustoconical surface and heat bonding said polyolefin film on said frustoconical surface.

63. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 61, wherein said method includes forming said thin polymeric film over said passage through said first end of said cartridge by stretching a polyethylene sheet taut over said first end of said cartridge and heat bonding said polyethylene sheet to said first end of said cartridge.

64. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 63, wherein said method includes stretching a first preferentially oriented polyethylene sheet over said first end of said cartridge and heat bonding said first preferentially oriented polyethylene sheet to said first end and stretching a second preferentially oriented polyethylene sheet over said second end of said cartridge and heat bonding said second preferentially oriented polyethylene sheet to said second end of said cartridge, wherein said first and second preferentially oriented polyethylene sheets on said opposed first and second ends of said cartridge are oriented at an angle other than parallel.

65. (Withdrawn) The method of making a cartridge for a medicament respiratory delivery device as defined in claim 64, wherein said method includes orienting said first and second preferentially oriented polyethylene sheets on said first and second ends of said cartridge at approximately 90 degrees.

66. (Original) A method of delivering a medicament to the respiratory system of a user, comprising the following steps:
providing a medicament respiratory delivery device including a cartridge having opposed inlet and outlet ends, a passage containing medicament extending through said cartridge

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and through said inlet and outlet ends, a thin burstable membrane having a burst pressure of between 1.2 and 10 atmospheres sealing said passage at said outlet end of said cartridge, and a manually compressible fluid delivery device communicating with said inlet end of said cartridge; and

compressing said manually compressible fluid delivery device to deliver fluid under pressure to said inlet end of said cartridge, rupturing said thin burstable membrane, entraining said medicament in said fluid, and delivering said medicament to the respiratory system of the user.

67. (Original) The method of delivering a medicament to the respiratory system of a user as defined in Claim 66, wherein said manually compressible fluid delivery device is a syringe including a barrel having an outlet communicating with said inlet end of said cartridge, a stopper reciprocable within said barrel and fluid between said outlet of said syringe and said stopper, said method including compressing said stopper to deliver fluid to said inlet end of said cartridge, rupturing said thin burstable membrane, entraining said medicament in said fluid and delivering said medicament to the respiratory system of the user.

68. (Original) The method of delivering a medicament to the respiratory system of a user as defined in Claim 67, wherein said cartridge includes a thin burstable membrane sealing said passage at said inlet end of said cartridge, wherein said method includes compressing said stopper in said barrel toward said outlet of said barrel, substantially simultaneously rupturing said thin burstable membranes at said inlet and said outlet of said cartridge and delivering said medicament to the respiratory system of the user.

69. (Original) A method of delivering a medicament to the respiratory system of a user as defined in Claim 66, wherein said manually collapsible compressible delivery device is a collapsible bulb having an inlet communicating with said inlet end of said cartridge and a fluid in said collapsible bulb, wherein said method includes collapsing said bulb, thereby delivering fluid to said inlet end of said cartridge, rupturing said thin

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burstable membrane, entraining said medicament in said fluid and delivering said medicament to the respiratory system of the user.

70. (Original) The method of delivering a medicament to the respiratory system of a user as defined in Claim 66, wherein said cartridge includes a thin polymeric burstable membrane sealing said passage at said first end of said cartridge having a burst pressure of less than 10 atmospheres, said method including compressing said manually compressible fluid delivery device to deliver fluid to said thin polymeric burstable membrane sealing said passage at said first end of said cartridge, substantially simultaneously bursting said membranes at said first and second ends, entraining said medicament in said fluid and delivering said medicament to the respiratory system of the user.

71. (Original) The method of delivering a medicament to the respiratory system of a user as defined in Claim 70, wherein said burstable membranes comprise preferentially oriented polyolefin films and such preferentially oriented polyolefin films at said inlet and outlet ends of said cartridge are oriented at an angle other than parallel, said method including rupturing said membrane at said inlet end of said cartridge in a first slit and substantially simultaneously rupturing said preferentially oriented polyolefin film at said second end of said cartridge in a second slit angularly related to said first slit, creating turbulence in said passage and entraining said medicament in said fluid and delivering said medicament to said respiratory system of the user

72. (Currently Amended) A cartridge for a respiratory medicament delivery device, comprising:

a body having opposed ends,

a passage through said body through said opposed ends wherein said opposed ends of said body surrounding said passage are convex,

a powdered medicament stored in said passage, and;

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burstable polyolefin membranes having a burst pressure less than 10 atmospheres covering, wherein said burstable polyolefin membranes are stretched taut over said convex opposed ends and are sealing said passage at said opposed ends of said body.

73. (Canceled)

74. (Currently Amended) The cartridge for a respiratory medicament delivery device as defined in Claim [73]72, wherein said opposed ends of said body are frustoconical adjacent said passage.

75. (Previously Presented) The cartridge for a respiratory medicament delivery device as defined in Claim 72, wherein said burstable membranes are formed of oriented polyolefin film and said oriented polymeric film covering and sealing said passage at said opposed ends of said body portion are oriented at different angles.

76. (Previously Presented) The cartridge for a respiratory medicament delivery device as defined in Claim 75, wherein said oriented polyolefin film at said opposed ends of said body portion are oriented at approximately right angles.

77. (Previously Presented) The cartridge for a respiratory medicament delivery device as defined in Claim 72, wherein said passage through said body of said cartridge is generally cylindrical.

78. (Previously Presented) The cartridge for a respiratory medicament delivery device as defined in Claim 77, wherein said body of said cartridge is generally cylindrical and said body includes an annular groove at a midportion of said body.

79. (Previously Presented) The cartridge for a respiratory medicament delivery device as defined in Claim 72, wherein said burstable polyolefin membranes are formed of polyethylene film having a thickness of between 0.3 and 1.5 mils and a burst pressure of less than 5 atmospheres.

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80. (Previously Presented) The cartridge for a respiratory medicament delivery device as defined in Claim 79, wherein said polyethylene film is uniaxially oriented polyethylene film having draw ratio of at least 1.2.

81. (Previously Presented) The cartridge for a respiratory medicament delivery device as defined in Claim 80, wherein said uniaxially oriented polyethylene film at said opposed ends of said body are oriented at approximately right angles.

82. (Previously Presented) The cartridge for a respiratory medicament delivery device as defined in Claim 72, wherein said burstable polyolefin membranes have a burst pressure of less than 5 atmospheres.

83. (Previously Presented) The cartridge for a respiratory medicament delivery device as defined in Claim 72, wherein said burstable polyethylene membranes have a burst pressure of between 1.5 and 4 atmospheres.

84. (New) A cartridge for a manually actuated respiratory medicament delivery device, comprising:

- a body having opposed ends,
- a passage through said body through said opposed ends,
- a medicament stored in said passage, and

burstable polyolefin membranes having a burst pressure less than 5 atmospheres covering and sealing said passage at said opposed ends of said body, wherein said burstable polyolefin membranes are formed of uniaxially oriented polyethylene film having a thickness of between 0.3 and 1.5 mils and having draw ratio of at least 1.2.

85. (New) The cartridge for a respiratory medicament delivery device as defined in Claim 84, wherein said uniaxially oriented polyethylene film at said opposed ends of said body are oriented at approximately right angles.

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86. (New) A cartridge for a manually actuated respiratory medicament delivery device, comprising:

a body having opposed ends,

wherein said body of said cartridge is generally cylindrical and said body includes an annular groove at a midportion of said body,

a passage through said body through said opposed ends,

wherein said passage through said body of said cartridge is generally cylindrical,

a medicament stored in said passage and burstable polyolefin membranes having a burst pressure less than 10 atmospheres covering and sealing said passage at said opposed ends of said body.

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